

EXHIBIT 6

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2 SUPREME COURT OF THE STATE OF NEW YORK
3 COUNTY OF SUFFOLK: PART 48
-----x

4 IN RE: OPIOID LITIGATION

5
6 INDEX NO.: 400000/2017
7 -----x

8 August 18, 2020
9 Central Islip, New York

10 MINUTES OF FRYE HEARING
11 (Testimony of James Rafalski)

12 BEFORE: HON. JERRY GARGUILLO
13 Supreme Court Justice

14 A P P E A R A N C E S:

15 SIMMONS HANLY CONROY, LLC
16 **Attorneys for Suffolk County**
17 112 Madison Avenue
18 New York, New York 10016
19 BY: PAUL J. HANLY, JR., ESQ.
20 JAYNE CONROY, ESQ.,
21 (212) 784-6401
22 phanly@simmonsfirm.com
jconroy@simmonsfirm.com

23 NAPOLI SHKOLNIK, PLLC
24 **Attorneys for Nassau County**
25 400 Broadhollow Road, Suite 305
Melville, New York 11747
BY: HUNTER SKOLNICK, ESQ.
SALVATORE C. BADALA, ESQ.
JOSEPH L. CIACCIO, ESQ.
(212) 397-1000
pnapoli@napolilaw.com
sbadala@napolilaw.com
jciaccio@napolilaw.com

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Q. And, sir, can I ask you to focus on my
questions. There's a regulation that contains that
requirement to report orders of unusual size,
pattern or frequency, correct?

3

A That is correct.

4

Q. You agree with me that that regulation
gives some guidance on a suspicious order, but you
think the actual full definition is up to the
registrar depending on a lot of factors, the scope
of their business, and the scope of those customers
that receive products from them?

5

A Yes, sir.

6

Q. For example, the regulation does not
tell distributors how to figure out if an order is
of unusual size, correct?

7

A That's correct.

8

Q. That's up to the registrar to define,
correct?

9

A Yes.

10

Q. There's no single generally accepted way
to say this is an order of unusual size, correct?

11

A There's not any language specific to
that statement, you mean, no, sir.

12

Q. There's no single generally accepted way

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to say this is an order of unusual frequency or
unusual pattern, correct?

4

A That is correct, sir.

5

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Q. And you're aware that government
watchdogs, some of the ones we talked about
yesterday, have recommended that it would be good
for the DEA to develop additional guidance for
distributors and manufacturers when it comes to
suspicious order monitoring and suspicious order
reporting?

12

13

A I am aware of that either publications
or that information, yes, sir.

14

15

Q. And you agree with that recommendation,
correct?

16

17

18

A Generally speaking, yes. Maybe not --
maybe you might interpret that question different
than me, but, yes, generally, yes.

19

20

21

22

23

24

25

Q. Using your words in terms of lack of
greater clarity from the DEA, the reason for the
lack of greater clarity from the DEA is that you
don't really think there's a one-size-fits-all
suspicious monitoring system or program, correct?

A Yes. I don't think I used that exact
terminology, but that concept would be consistent

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for the way that I answered about that, yes, sir.

3

Q. There's no one-size-fits-all suspicious
order monitoring system, correct?

4

A Yes, that's correct. Yes, sir.

5

Q. Even today distributors or manufacturers
are left to design their own suspicious order
monitoring programs, correct?

6

A They are, yes, sir.

7

Q. And there's no generally accepted system
saying this is exactly what a suspicious order
monitoring system has to look like, correct?

8

A That's correct.

9

Q. As a result every distributor and every
manufacturers' suspicious order monitoring programs
are different from each other, right?

10

A Yes. Yes. In some ways there are some
differences.

11

Q. And you read, as part of your
preparation in this case, testimony from the DEA's
former head of Office of Diversion Control, Joe
Rannazzisi, correct?

12

A I have read some of his deposition
testimony, yes, sir.

13

Q. I take it you saw that when he was asked

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about giving guidance or giving a checklist to registrants as to what's required to be in a suspicious order monitoring system, he said that's a business decision based on what the registrant's needs are, and the Drug Enforcement Administration does not tell a registrant what that specific system should look like.

9

10

Do you remember seeing that testimony from him?

11

12

13

A I do not recall that. I could review it, if you'd like, but I don't disagree with that statement.

14

15

16

17

18

19

20

21

Q. Well, that's where I was going. Maybe I can short circuit it. Do you agree with the idea that when it comes to designing a suspicious order monitoring system, that's a business decision based on what the registrant's needs are, and the Drug Enforcement Administration does not tell a registrant what that specific system should look like?

22

A I agree with that statement.

23

24

Q. And I lost you for a second. Did you say you agree with that statement?

25

A I did. I agree with that statement,

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Opioid Frye Hearing

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sir.

3

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Q. Evaluating suspicious order monitoring
programs has to involve a company-by-company
assessment, correct?

5

6

A You mean a customer-by-customer
assessment?

7

8

Q. And companies by companies in terms of
their business and who they're dealing with.

9

10

A Yes. Yes, sir.

11

12

13

Q. What works for one distributor or
manufacturer in your view may not necessarily work
for another, correct?

14

15

16

17

A It may work, but I don't think that I
would impose one system from one company on another,
but, certainly there are some businesses that are
very similar that potentially they could work.

18

19

20

Q. In your report you lay out some I think
you call it key components that you believe should
be included in a suspicious order monitoring system.
Are you aware of that?

21

22

A In my report?

23

Q. Yes, sir.

24

25

A I don't know if I say they should be
included, if that's my exact language. I think that

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Opioid Frye Hearing

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I might say that one would expect to see, but yes,
3 sir.

4

Q. Well, actually that's where I'm going,
5 is it possible to have a compliant suspicious order
6 monitoring system without all of those components?

7

A Depending on the scope of business or
8 the type of customer, I think it's possible to not
9 include some of those things.

10

Q. Okay. There are no -- stated
11 differently -- there are no generally accepted set
12 of requirements that every single suspicious order
13 monitoring program must have, correct?

14

A Correct statement.

15

Q. Let's look at Plaintiff's Exhibit 1.
16 Chris, it's Tab 1 in the binder that we -- it's Tab
17 1 in our document set that we used yesterday.

18

This is your report, Mr. Rafalski, and
19 could we put that up on the screen, please? Page
20 45, please. You have a section of your report that
21 says, Analysis of the methodologies to quantify
22 suspicious orders distributed in New York. Do you
23 see that?

24

A Yes, sir.

25

Q. And if you look down near the bottom

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2 review.

3 Q. Okay. I want to go back to your
4 methods. You talked a lot yesterday about what you
5 did while you were at the DEA. Am I correct that
6 while you were at the DEA, the DEA never analyzed
7 ARCOS data using the methodologies that Dr. McCann
8 presented and you also presented in your report?

9 A That exact specific scenario, no, sir.

10 Q. You never used those methodologies,
11 correct?

12 A No, sir.

13 Q. And I think the way I'm asking the
14 question, I just want to make sure we're not talking
15 past each other. What I said is correct, yes?

16 A I never specifically applied these
17 methodologies during one of my occasions, and I'm
18 not aware that the DEA did. I'm not saying they
19 didn't, but typically these methodologies, no, sir.

20 Q. Thank you. Before I dive into
21 Methodology A, which is the one I'm going to focus
22 on because it's the one that you rely on, I want to
23 cover some general points about your work regarding
24 flagged orders and suspicious orders.

25 And let's go back to Plaintiff's Exhibit

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diligence file.

3

Q. That's true for all distributors?

4

A Yes, sir.

5

Q. That's true for all manufacturers?

6

A Yes, sir.

7

Q. That's true for pharmacy Defendants in
this case?

8

A Every specific due diligence file,
that's a correct statement, yes, sir.

9

Q. You told us yesterday that it is
absolutely important that there be an uninterrupted
supply of prescription opioids for patients who need
them. Do you recall that testimony?

10

A I stand by that statement.

11

Q. You agree that manufacturers and
distributors and pharmacies play an important role
in ensuring an adequate and uninterrupted supply of
legitimate prescription opioids, correct?

12

A Yes, sir.

13

Q. And relevant to ensuring the
distributors and pharmacies and manufacturers play
that role, that critical role in ensuring an
adequate and uninterrupted supply of legitimate
prescription opioids, you don't have an estimate as

14

1 Opioid Frye Hearing

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2 to how much of prescribing or prescriptions are
3 legitimate in terms of prescription opioids?

4 A I wasn't requested to conduct that
5 analysis so, no, sir, I do not.

10 Frye analysis over here, and, of course,
11 examination during the trial of foundational
12 material.

13 It seems to the Court, and perhaps it's
14 far from me to question your needs and
15 methods -- pardon the play on the words
16 gentlemen and ladies -- what's the
17 connection?

24 It seems to the Court that a great deal
25 of your examination is dealing with the

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Now, was it -- did they use specifically
a, you know, methodology or diagnostic tool A, B, C,
or D, no, but within the DEA, I believe the same
type of analysis was conducted to come to some
conclusion on some of the cases, yes, sir.

7

Q. Okay. That's not my question, sir.

8

Please focus on my question. Can you point me to
any time you're aware of when anyone has used Method
A to try to estimate, not flagged orders, not even
suspicious orders, but actually diverted orders?

12

Yes or no.

13

A No.

14

Q. Is it generally accepted? Is there any
measure of general acceptance you can point me to
for using Method A to estimate, not flagged orders,
not suspicious orders, but actually diverted orders,
as you have done in your testimony?

19

A No.

20

Q. Are you aware that the DEA has actually
used techniques to try to estimate the amount of
diversion?

23

A Yes.

24

Q. And are you aware of the numbers that
they have come up with when they use those

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A Yes, sir.

3

4

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6

Q. We can take that title down. If you look across the top, there's a year of -- there's a range of years. I'm going to focus on what DEA was focused on, 2018. Do you see that?

7

A Yes.

8

MR. SCHMIDT: And I'm sorry that this is not the most elegant way to be able to show this to you. It's hard doing this remotely, but, Chris, could we call out the line for hydrocodone sale and oxycodone sale, please.

13

BY MR. SCHMIDT:

14

Q. And I hope you can see this with me, Mr. Rafalski. I just want to lay out what the math is, and then I'll tell you what I get from these numbers.

18

The hydrocodone estimated diversion from the DEA is, if we look at the left, 24.259. Do you remember that number?

21

A Yes.

22

Q. And if we divide that by the 2018 number for total hydrocodone it's 43,027.640, correct?

24

A Yes, sir.

25

Q. And that comes up to .056 percent. Does

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that sound right to you?

3

A Yeah. I wouldn't argue with that. I'm not going to calculate it, but...

5

Q. And let's just do the same for oxycodone. It's kind of covered, if you can pull the left side down a little bit, Chris. There we go.

9

So for oxycodone the amount of diversion for 2008 is 57.051; do you see that?

11

A Yes, sir.

12

Q. Divided by 79,596.606. Do you see that?

13

A I don't see the .606. Is that the calculation you're doing?

15

Q. No. That's the number at the end of --

16

THE COURT: It's a suggested calculation.

18

MR. SCHMIDT: No, it's actually not.

19

That's the number reported in Exhibit I of the table. It's probably hard to read.

21

Maybe we can blow up that number a little bit, the 79,596.606 under 2018, Chris.

23

BY MR. SCHMIDT:

24

Q. Do you see that?

25

A I can see that number, but my

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Q. Okay. And you don't have alternative
numbers using either their methodology or any other
methodology for actual diversion for years other
than 2018, correct?

3

A I do not.

4

Q. Okay. Let me go back to some of the
questions I was asking you. Do you know if any of
the orders that were flagged by Dr. McCann's
methodology that you adopted, do you know if any of
those orders were actually diverted?

5

A When you say the word "actually," I have
to answer that no, sir.

6

Q. You don't know?

7

A No, sir.

8

Q. To the contrary, would you agree with me
that just a suspicious order in an amount outside of
the normal, which is either an amount that's a large
order, orders that are frequent orders, or the other
criteria that's listed in the regulation, that in
itself doesn't mean guarantee that it's going to be
put into an illicit market?

9

Do you agree with that? And I'll just
ask, I don't know if you heard the end of what I
said. Someone was not on mute, so I'll just ask

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you turned in this report, did you?

3

A Well, your first question was pretty broad. Specifically about this report, no, sir.

5

Q. You didn't read his deposition in the New York case, did you?

7

A I read portions of it.

8

Q. But not in its entirety?

9

A No, not the entirety.

10

Q. You've not checked his calculations,

11 have you?

12

A Definitely I have not done that, sir.

13

Q. And in terms of what we see on this page, your Method A, this is, again, copied in this case word for word and number for number from what Dr. McCann did, correct?

17

A That would be my expectations, yes, sir.

18

Q. You didn't change anything?

19

A I did not.

20

Q. And even the format that this appears in, that was given to you and adopted by you as your own, in your words, correct?

23

A The Excel spreadsheet system, yes, I didn't design this. That's correct.

25

Q. You didn't know, until we talked at your

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deposition, that in coming up with these numbers and
3 getting from the data to the opinions you offered,
4 the methodology he used that you adopted, you didn't
5 know until we talked at your deposition that he had
6 to make some judgment calls in coming up with these
7 numbers, did you?

8

A So I remember that testimony, and I
think there were some -- I think the term that was
used was assumptions, and I was a little confused by
that.

12

I know there was some questions on how
13 to apply the methodology, and I -- so I may have
14 answered that I did not know, but I think I was
15 confused by the question.

16

Q. You knew his algorithm required certain
judgment calls?

18

A Well, I had some discussions or -- not
directly with him in regards to the start and stop
20 point, whether it was 30 days or whether it was
21 calendar months, but specifically I know there was a
22 little bit of he needed to make some assumptions or
23 judgments to run it, but specifically, I didn't have
24 any conversations directly with him about it.

25

Q. And you can't say, one way or another,

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2 whether you agree with the judgment calls he made in
3 performing his algorithm, correct?

4 A That's not a totally true statement. So
5 on applying the Methodology A, if you went by the
6 calendar months, I would agree. I agree with that.

7 Q. Is it true that you don't know the
8 entirety of his judgment calls?

9 A I reviewed his deposition testimony. If
10 there's some outside of that, I would not be aware
11 of them.

12 Q. Okay. Let's look at your February 7th,
13 2020 deposition transcript, page 204, line 13 to 22.
14 This is Tab 2, page 204, 13 to 22.

15 "QUESTION: Okay. Maybe that answers my
16 next question, which is do you know, can you
17 say one way or the other whether you agree
18 with the judgment calls he made in performing
19 his algorithm?

ANSWER: I don't know the entirety of his judgment call, so I can't, I can't answer that question."

Did I read that correctly?

24 A You did.

25 Q. Do you recall being asked that question

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and giving that answer at your deposition?

3

A I don't specifically recall it, but I
don't dispute the deposition record.

5

Q. Do you dispute the truth of that
statement?

7

A Yes, sir.

8

Q. You do dispute the truth of that
statement that you made?

10

A I do not. I'm sorry.

11

Q. Okay. And you looked at his testimony.
Do you see the part of his testimony where he said,
I probably would come up with 5 or 10 different
small decisions that needed to be made in order to
operationalize it? Did you see that portion of his
testimony?

17

A I don't specifically recall that.

18

Q. Okay. Do you know what the 5 to 10
decisions he had to make to be able to perform his
Method A calculation that you relied on? Do you
know what those 5 to 10 decisions were?

22

A No, sir.

23

Q. So not knowing how he took the data and
made the 5 to 10 decisions, you don't know how far
of a gap there is between his outputs and that

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2 additional data in terms of those 5 to 10 decisions
3 that he made. Am I correct in that?

4 A Yes, sir. That's correct. That is a
5 correct statement.

6 Q. Now, let's show the Judge how your
7 method works in application. Under your Method A,
8 you look to see if the level of opioids in a given
9 month is more than any in the prior single six
10 months, right?

11 A Trailing six months, yes, sir.

12 MR. SCHMIDT: And if we illustrate that,
13 can we pull out Demonstrative Exhibit 4?
14 We'll mark this as Court Exhibit K. Let me
15 just give a moment for it to be passed out in
16 court.

17 BY MR. SCHMIDT:

18 Q. So do you see I've written up on the
19 screen, Year 1. I start in February, 5,000, go
20 through July, and the number of pills vary per
21 month, 5,000, 10,000, 7,000, 8,000, 9,500. Do you
22 see that?

23 A I do.

24 Q. And do you recognize that these are the
25 very same numbers that Dr. McCann gives as an